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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,283	07/14/2000	Timothy T. Goodnow	109. 111. 114	6499
28120	7590	04/14/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 04/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,283

Applicant(s)

GOODNOW, TIMOTHY T.

Examiner

Ja-Na Hines

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,14-18,26,27 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3-8 is/are allowed.
- 6) ☒ Claim(s) 14-18,26,27 and 29-35 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed January 5, 2004 has been entered. Claims 1, 4-8, 14, 17-18 and 26 have been amended. Claims 2, 9-13, 19-25 and 28 have been cancelled. Claims 1, 3-8, 14-18, 26-27 and 29-35 are under consideration.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments, arguments and affidavit submitted by Dr. Klein:

- a) The enablement rejection of claims 1-8, 14-18, 23 and 25-35 under 35 U.S.C. 112, first paragraph;
- b) The rejection of claims 1, 3-6, 14-17, 23, 25, and 27-35 under 35 U.S.C. 103(a) as being unpatentable over McLaughlin, Erich et al., Tadler et al., and Fisher et al.;
- c) The rejection of claims 2 and 15 under 35 U.S.C. 103(a) as being unpatentable over McLaughlin, Erich et al., Tadler et al., and Fisher et al., as applied to claims 1 and 14 above, and further in view of Chang et al., (US Patent 5,200,323; and
- d) The rejection of claims 7 and 17 under 35 U.S.C. 103(a) as being unpatentable over Tadler et al., (1989) and Fisher et al.

Response to Arguments

3. Applicant's arguments with respect to claims 14-18, 26-27 and 29-35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The independent claim recites the donor blood/blood product or donor tissue from the donor mammal determined to have less than 1×10^6 CFU per mL of Gram-positive and/or Gram-negative bacteria, ~~then~~ claim 29 recites wherein the clinically effective amount of bacteria is greater than 1×10^6 of blood or blood product.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14-17, 26-27 and 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claims 14 and 18 is drawn to a method for screening for the presence of a clinically relevant amount of Gram-positive and/or Gram-negative bacteria in a donor tissue from a donor mammal useful for transfer to a recipient mammal, however the last wherein clause within the method is drawn to ...the donor blood or blood product from the donor mammal determined to have less than 1×10^6 CFU per mL of Gram-positive and/or Gram-negative bacteria is useful for transfer to the recipient mammal. The preamble is referring to donor tissue and not donor blood. Thus, there

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is no correlation between the donor tissue and donor blood. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn screening for the presence of a clinically relevant amount of Gram-positive and/or Gram-negative bacteria in a donor tissue from a donor mammal useful for transfer to a recipient mammal. Clarification is required to overcome the rejection.

6. Claim 27 recites alternative limitations which are improperly expressed.

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

7. Claim 29 recites the limitation "wherein the clinically effective amount of bacteria is greater than 1×10^6 of blood or blood product. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 29-35 are unclear. The claims are dependent upon claims 14, 17 and 18 which refer to methods of screening donor tissue, however claims 29-35 recites having clinically relevant amount of bacteria only in blood or blood products. Therefore the claims are unclear, the since 14, 17 and 18 are not drawn to blood or blood products. Clarification is required to overcome the rejection.

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Allowable Subject Matter

9. Claims 1 and 3-8 are allowable.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859.

The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
April 6, 2004


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